DR VIJAENDREH SUBRAMANIAM & ANOR v. KERAJAAN MALAYSIA & ANOR

HIGH COURT MALAYA, KUALA LUMPUR
AHMAD KAMAL MD SHAHID J
[ORIGINATING SUMMONS NO: WA-24-46-09-2021]
30 AUGUST 2022

Abstract – *(i) The purpose of pleadings is to give fair notice of the case to be made and to limit and define the issues. Its object is to prevent the issues from being enlarged, which would prevent either party from knowing when the cause came on for trial and what the real point to be discussed and decided was; and (ii) It is within the jurisdiction of the legislature and the executive to declare the legitimacy of the use of drugs on humans. It is not within the powers of the court to declare so as the court does not determine policy issues in the field of scientific and technical expertise.*

CIVIL PROCEDURE: *Pleadings – Rules on pleadings – Reliefs sought in originating summons ('OS') broadly framed as 'interpretation' and 'determination' – Specific declarations sought not pleaded in OS and only raised in submissions – Whether submissions differed from nature and scope of pleaded claim in OS – Whether nature and scope of claim must be confined to what was expressly pleaded in OS – Whether additional prayer ought to be entertained by court*

CIVIL PROCEDURE: *Reliefs – Language – Omission to pray one of reliefs in Bahasa Melayu version compared to in English – Whether sufficient reasons given for failure – Whether court ought to allow said relief*

CIVIL PROCEDURE: *Originating summons – Interpretation and determination – Interpretation of provisions in Poisons Act 1952 and Poisons Regulations 1952 and determinations on whether registered medical practitioner entitled to dispense Ivermectin to patients – Whether originating summons attempt to move civil court to pre-empt, impede and/or interfere with on-going criminal investigations – Whether OS attempt to move court to make new public health policy to permit use of unregistered poison*

The plaintiffs were qualified medical practitioners. The first plaintiff was also the President of the Malaysian Association for the Advancement of Functional and Interdisciplinary Medicine ('MAAFIM') and he brought this action on behalf of himself and all the other members of MAAFIM. A group of officers of the Pharmaceutical Services Division from the Health Department of Selangor had confiscated Ivermectin medicines from the second plaintiff's clinic. The second plaintiff is currently under investigation for potential offences under the Poisons Act 1952 ('Act') and Control of

Drugs and Cosmetics Regulations 1984 concerning the dispensation of Ivermectin over the counter at his clinic. The plaintiffs filed originating summons ('OS') to seek an interpretation of the provisions in the Act and the Poisons Regulations 1952 ('Regulations') and determinations on whether a registered medical practitioner is entitled to dispense Ivermectin to patients pursuant thereto. Nevertheless, in the plaintiffs' submissions, the plaintiffs prayed for the following declarations that, *inter alia*: (i) a registered medical practitioner is entitled to dispense Ivermectin as an ingredient to his or her patient under the Act and Regulations; (ii) a registered medical practitioner can dispense Ivermectin to his or her patients for the purposes of the medical treatment of such patient only and in compliance with s. 19 of the Act and the Regulations; and (iii) the Sale of Drugs Act 1952 ('SDA') and the regulations enacted thereunder did not prohibit a fully registered medical practitioner from dispensing Ivermectin to his or her patient in accordance with his professional judgment and in compliance therewith. The issues that arose were: (i) whether the plaintiffs' claim must only be confined to what was expressly pleaded in the OS; (ii) the plaintiffs' omission to pray for one of the reliefs in the Bahasa Melayu version compared to that in English; (iii) whether the OS was an attempt to move the civil court to pre-empt, impede and/or interfere with the ongoing criminal investigation against the second plaintiff; and (iv) whether the OS was an attempt to move this court to make a new public health policy to permit the use of an unregistered poison for the treatment of COVID-19, contrary to the regulatory regime and the policy of the second defendant.

Held (dismissing OS):

(1) At the outset, it was apparent that the plaintiffs' claim from the submissions differed from the nature and scope of the pleaded claim in the OS. The reliefs sought in the OS were broadly framed as 'interpretation' and 'determination'. The specific declarations sought were not pleaded in the OS and were only raised in the plaintiffs' submission. The 'interpretation' and 'determination' prayed for in the OS were in respect of the Act and the Regulations only. The plaintiffs now attempted, by way of submission, to insert an additional prayer for a declaration in respect of the SDA and the regulations enacted thereunder. The nature and scope of the plaintiffs' claim must be confined to what was expressly pleaded in the OS. The additional prayer raised by the plaintiffs ought not to be entertained by this court. (paras 14-16, 23 & 25)

(2) The plaintiffs had added a relief in para. (d) in the English version of the OS when the same was not provided for in the Bahasa Melayu version of the OS. The plaintiffs did not inform this court of their intention to amend the OS by inserting the relief claim nor were there

A any sufficient reasons given for the failure to state the relief sought in the Bahasa Melayu version when it was prayed for in the English version. The failure of the plaintiffs in praying for the reliefs in the national language meant that this court ought not to allow that said relief which was provided for the same in para. (d) of the English version. Even though the English version provided for such relief, this court was bound to give precedence to the Bahasa Melayu version. (paras 26 & 30)

(3) The filing of this present OS was an abuse of the court process as there existed a collateral purpose of interfering with the criminal investigation conducted against the second plaintiff. Determining the reliefs claimed by the plaintiffs would lead, or potentially lead, this court to pre-empt, impede and/or interfere with the on-going criminal investigations against the second accused. It was not the role of the civil court to usurp the jurisdiction of the criminal courts and the prosecutorial discretion of the Public Prosecutor. (paras 42, 44 & 68)

(4) With the use and effect of the Ivermectin drugs still pending further clinical research at the World Health Organisation (WHO) with no assurance that Ivermectin could be used to cure COVID-19, it was defying the interest of justice to legitimise the use and dispensation of Ivermectin by registered medical profession under the Act and the Regulations. It was within the jurisdiction of the Legislature and the Executive to make such a declaration of the legitimacy of the use of Ivermectin on humans and it was not within the powers of this court to do so. (para 67)

Case(s) referred to:

Ambank (M) Bhd v. Luqman Kamil Mohammed Don [2012] 3 CLJ 551 FC ***(refd)***

Athvale v. New South Wales [2021] FAC 1075 ***(refd)***

Cheow Chew Khoon v. Abdul Johari Abdul Rahman [1995] 4 CLJ 127 CA ***(refd)***

Datuk Syed Kechik Syed Mohamed v. Government Of Malaysia & Anor [1978] 1 LNS 44 FC ***(refd)***

Dr Michael Jeyakumar Devaraj v. Peguam Negara Malaysia [2013] 2 CLJ 1009 FC ***(refd)***

Government Of Malaysia v. Lim Kit Siang & Another Case [1988] 1 CLJ 219; [1988] 1 CLJ (Rep) 63 SC ***(refd)***

Kassam And Others v. Hazzard And Others [2021] 393 ALR 664 ***(refd)***

Lai Soon Onn v. Chew Fei Meng & Other Appeals [2018] 10 CLJ 48 CA ***(refd)***

Munchy Food Industries Sdn Bhd v. Huasin Food Industries Sdn Bhd [2021] 10 CLJ 329 FC ***(refd)***

Murshid Meam Ghouse Meam & Ors v. Genneva Malaysia Sdn Bhd [2018] 1 LNS 1524 CA ***(refd)***

Poraviappan Arunasalam Pillay (Sebagai Pentadbir Harta Pesaka Nadajarah Sithambaram Pillai) v. Periasamy Sithambaram Pillai & Anor [2015] 6 CLJ 857 FC ***(refd)***

Protasco Bhd v. PT Anglo Slavic Utama & Ors [2020] 1 LNS 997 HC ***(foll)***

Rekha Munisamy v. Ortus Expert White Sdn Bhd & Anor [2021] 7 CLJ 353 CA ***(refd)***
SD v. Royal Borough Of Kensington And Chelsea [2021] EWCOP 14 ***(refd)***
United Malayan Banking Corp Bhd v. Palm & Vegetable Oils (M) Sdn Bhd & Ors [1982] CLJ 547; [1982] CLJ (Rep) 358 FC ***(refd)***

Legislation referred to:
Control of Drugs and Cosmetics Regulations 1984, regs. 7(1), 15(2)
Poisons Act 1952, s. 19
Rules of Court 2012, O. 2 r. 1(1), O. 92 r. 1(1)

For the plaintiffs - Gurdial Singh Nijar, SP Chandra, Abraham Au & Lim Zi Han; M/s Yeoh Mazlina & Partners
For the defendants - Suzana Atan & Liew Horng Bing; SFC's & Saravana Kuppusamy; FC

Reported by Lina E

JUDGMENT

Ahmad Kamal Md Shahid J:

Introduction

[1] The plaintiffs on 21 September 2021 filed an originating summons (OS) to seek interpretation of provisions in the Poisons Act 1952 and the Poison Regulations 1952 and determinations on whether a registered medical practitioner is entitled to dispense Ivermectin to patients pursuant thereto.

[2] The plaintiffs seek the following reliefs:

(a) Pentafsiran peruntukan-peruntukan:

(i) Akta Racun 1952 termasuk ss. 2, 12(1)(c), 18(1)(c), 19 dan 21(1) dan (2); dan

(ii) Peraturan-peraturan Racun 1952 termasuk Jadual Pertama Bahagian 1 Kategori B;

(b) Satu penentuan sama ada seorang pengamai perubatan adalah berhak untuk mendispens (dispense) Ivermectin sebagai suatu bahan ramuan kepada pesakit-pesakitnya di bawah Akta Racun 1952 dibaca bersama dengan Peraturan-peraturan Racun 1952;

(c) Satu penentuan sama ada seorang pengamai perubatan boleh mendispens Ivermectin kepada pesakit-pesakitnya bagi tujuan rawatan perubatan pesakit tersebut sahaja dan selaras dengan s. 19 Akta Racun 1952 Peraturan-peraturan Racun 1952;

(d) Kos; dan

(e) Lain-lain relif yang mana mahkamah yang mulia ini anggap sesuai, wajar dan adil, *inter alia*, bidang kuasa sedia ada mahkamah yang mulia ini.

[3] After the hearing, I dismissed the plaintiffs' OS (encl. 1). This judgment will contain the full reasons for the dismissal.

Background Facts

[4] The first plaintiff is a qualified medical practitioner registered under the Medical Act 1971 and is a specialist consultant doctor at Mahkota Medical Centre Sdn Bhd. He is also the President of the Malaysian Association for the Advancement of Functional and Interdisciplinary Medicine (MAAFIM) and brings this action on behalf of himself and all other members of MAAFIM.

[5] MAAFIM is a national association registered under the Societies Act 1966. Its members are medical registered practitioners with varied specialist training in a diverse range of medical fields. MAAFIM's aims are as follows:

(i) to facilitate the advancement of science, research, education and further training, to support best and evidence-based medical care and to provide advice on policy in the realm of Interdisciplinary Medicine (the interaction between conventional and complementary medicine based on evidence-based results); and

(ii) to set the standard of practice under various subcommittees in all the areas of Interdisciplinary Medicine.

[6] The second plaintiff is a qualified and registered medical practitioner under the Medical Act 1971 and operates a clinic under the name Klinik Medik at 9156, Jalan Bandar 4, Taman Melawati, 53100 Kuala Lumpur. He is also a member of MAAFIM.

[7] On 14 June 2021, a group of officers of the Pharmaceutical Services Division from the Health Department of Selangor confiscated Ivermectin medicines from the second plaintiff's clinic. According to the plaintiffs, they have the *locus standi* to initiate this OS because the first plaintiff is a respectable body of registered medical practitioners that are directly affected by the act of the defendants. This is further buttressed by the fact that the Ivermectin medicines were confiscated from the clinic of the second plaintiff and the subsequent public warnings by the authorities about dispensing Ivermectin by registered medical practitioners. The legality of the authorities' act is not the subject of this OS.

[8] The second plaintiff is currently under investigation by the Pharmacy Services Division of the Selangor Health Department for potential offences under the Poisons Act 1952 and Control of Drugs and Cosmetics Regulations 1984 concerning the dispensation of Ivermectin over the counter at his clinic.

The Decision Of The Court

[9] Having perused the cause papers and submissions of both parties, I am of the view that the plaintiffs' OS is misconceived and without merit for the following reasons:

(i) the plaintiffs' claim must only be confined to what was expressly pleaded in the OS;

(ii) the purpose and effect of the plaintiffs' claim are to pre-empt and interfere with the ongoing criminal investigation against the second plaintiff by determining the question of criminality. It is not the role of the civil court to usurp the jurisdiction of the criminal courts and the prosecutorial discretion of the Public Prosecutor; and

(iii) the essence of the plaintiffs' claim is for this court to make a new public health policy in respect of Ivermectin, contrary to the regulatory framework and Government policy. It is not the role of the court to determine policy issues in the field of scientific and technical expertise, especially in the rapidly evolving circumstances of the COVID-19 pandemic.

Whether The Plaintiffs' Claim Must Only Be Confined To What Was Expressly Pleaded In The OS

[10] The reliefs prayed in the plaintiffs' OS are as follows:

(a) Pentafsiran peruntukan-peruntukan:

(i) Akta Racun 1952 termasuk seksyen 2, 12(1)(c), 18(1)(c), 19 dan 21(1) dan (2); dan

(ii) Peraturan-peraturan Racun 1952 termasuk Jadual Pertama Bahagian 1 Kategori B;

(b) Satu Penentuan sama ada seorang pengamal perubatan adalah berhak untuk mendispens (dispense) Ivermectin sebagai suatu bahan ramuan kepada pesakit-pesakitnya di bawah Akta Racun 1952 dibaca bersama dengan Peraturan-peraturan Racun 1952;

(c) Satu Penentuan sama ada seorang pengamal perubatan boleh mendispens Ivermectin kepada pesakit-pesakitnya bagi tujuan rawatan perubatan pesakit tersebut sahaja dan selaras dengan seksyen 19 Akta Racun 1952 Peraturan-peraturan Racun 1952;

(d) Kos; dan

(e) Lain-lain relif yang mana Mahkamah yang Mulia ini anggap sesuai, wajar dan adil, *inter alia*, bidang kuasa sedia ada Mahkamah yang Mulia ini.

[11] The English translation of the plaintiffs' OS is as follows:

(a) The interpretation of the provisions of:

(i) the Poisons Act 1952 including sections 2, 12(1)(c), 18(1)(c), 19 and 21(1) and (2); and

(ii) the Poison Regulations 1952 including the First Schedule Part 1 Category B.

(b) A Determination of whether a registered medical practitioner is entitled to dispense Ivermectin as an ingredient to his or her patient under the Poisons Act 1952 read together with the Poison Regulations 1952.

(c) A Determination of whether a registered medical practitioner can dispense Ivermectin to his or her patients for the purposes of the medical treatment of such patient only and in compliance with section 19 of the Poisons Act 1952 and the Poison Regulations 1952.

(d) Declarations, as appropriate, ensuing from the determinations and interpretation as aforesaid.

(e) Costs; and

(f) Such further or other relief which this Honourable Court deems fit, appropriate and just to order under, *inter alia*, the inherent jurisdiction of this Honourable Court.

[12] Nevertheless, in the plaintiffs' submission, the plaintiffs prayed that the court makes the following declarations:

(a) That a registered medical practitioner is entitled to dispense Ivermectin as an ingredient to his or her patient under the Poisons Act 1952 and the Poisons Regulations 1952;

(b) That a registered medical practitioner can dispense Ivermectin to his or her patients for the purposes of the medical treatment of such patient only and in compliance with section 19 of the Poisons Act 1952 and the Poison Regulations 1952;

(c) That the Sale of Drugs Act 1952 and Regulations enacted under it does not prohibit a fully registered medical practitioner from dispensing Ivermectin to his or her patient in accordance with his professional judgment and in compliance therewith;

(d) Costs; and

(e) Such further or other relief which this honourable court deems fit, appropriate and just to order under *inter alia*, the inherent jurisdiction of this honourable court.

[13] The defendants raised a preliminary objection that in the sealed OS, the plaintiffs did not pray for any declaration, order or any other specific relief other than the interpretation and the determination of the two questions above.

[14] At the outset, it is apparent that the plaintiffs' claim from the submissions differs from the nature and scope of the pleaded claim in the OS.

[15] The reliefs sought in the OS were framed broadly as "interpretation" and "determination". The specific declarations sought were not pleaded in the OS and were only raised in the plaintiffs' submission.

[16] The "interpretation" and "determination" prayed for in the OS were in respect of the Poisons Act 1952 and the Poison Regulations 1952 only. The plaintiffs now are attempting by way of submission to insert an additional prayer for a declaration in respect of the Sale of Drugs Act 1952 and the regulations enacted thereunder.

[17] The OS did not seek any relief in respect of the legality of the drug enforcement measures taken against the second plaintiff or the validity of the circular (exh. "VJD4"). However, the plaintiffs in their affidavit and submission seek to challenge the legality and validity of those Acts, *albeit* couched in an ambiguous and collateral manner.

[18] It is well settled that the court should not decide on an issue that was not pleaded by the parties. Where a vital issue was not raised in the pleadings it cannot be allowed to be argued and to succeed on appeal (see *Ambank (M) Bhd v. Luqman Kamil Mohammed Don* [2012] 3 CLJ 551; [2012] 3 MLRA 459; [2012] 3 MLJ 1, *Poraviappan Arunasalam Pillay (Sebagai Pentadbir Harta Pesaka Nadajarah Sithambaram Pillai) v. Periasamy Sithambaram Pillai & Anor* [2015] 6 CLJ 857; [2015] 4 MLRA 275; [2015] 4 MLJ 285; [2015] 4 AMR 445).

[19] The purpose of pleadings is to give fair notice of the case which is to be made, and to limit and define the issues. Its object is to prevent the issue from being enlarged, which would prevent either party from knowing when the cause came on for trial, and what the real point to be discussed and decided was.

[20] In *Murshid Meam Ghouse Meam & Ors v. Genneva Malaysia Sdn Bhd* [2018] 1 LNS 1524; [2018] MLJU 1408; [2018] MLRAU 380; [2018] 8 AMR 29, Hasnah Mohammed Hashim JCA (now FCJ) held as follows:

> [23] *The main objective of particulars in pleadings is to ensure that the overriding principle that the litigation between the parties, and particularly the trial, should be conducted fairly, openly and without any surprises – to inform the other side of the nature of the case that they have to meet,* as distinguished from the manner in which that case is to be proved, to limit the generality of the allegations in the pleadings, or to define the issues which have to be tried and for which discovery is required. *Each party is entitled to know the case that is intended to be made against him at the trial and have such particulars of his opponent's case as this will prevent him from being taken by surprise.* The particulars pleaded is to enable the other party to decide what evidence he ought to be prepared with and to prepare for the trial. (emphasis added)

[21] Any omission or defect in the pleadings cannot be made good by affidavit evidence, much less by way of submission. Raja Azlan Shah AG LP (as the late Royal Highness then was) highlighted this in *United Malayan Banking Corp Bhd v. Palm & Vegetable Oils (M) Sdn Bhd & Ors* [1982] CLJ 547; [1982] CLJ (Rep) 358; [1983] 1 MLJ 206; [1982] 1 MLRA 720; as follows:

A [6] As we have said earlier the deposit of the shares as security was not disclosed in the Statement of Claim when the action was instituted nor was the fact that the security had been realised in a series of sales of the shares between January and September 1980, and these matters were only disclosed for the first time in June 1981 in the affidavit in support of the Order 14 Summons. This omission is
B surprising, to say the least, and we cannot but observe that **any defect or omission in the Statement of Claim cannot be made good by affidavit evidence:** *Gold Ores Reduction Co v. Parr* [1892] 2 QB 14 where Mathew J, said that **"it is most important that a defendant should know from the writ what the exact claim against him is"**.
C The respondents also complain of the timing of the sale and the price realised and we would on this aspect refer to *Cuckmere Brick Co Ltd & Anor v. Mutual Finance Ltd* [1971] Ch 949 (which was applied in *Duke v. Robson* All ER 481 488) that the duty of a mortgagee to a mortgagor when exercising his power of sale is to take reasonable care to obtain a proper price, a duty which has since been extended
D by the English Court of Appeal to guarantors as well in *Standard Chartered Bank v. Walker & Anor* dated June 21, 1982. We would add that even after the sale of the shares there was and has been no attempt to amend the Statement of Claim to reflect the true position. (emphasis added)

E **[22]** In the latest Federal Court decision in *Munchy Food Industries Sdn Bhd v. Huasin Food Industries Sdn Bhd* [2021] 10 CLJ 329; [2022] 1 MLJ 377; [2022] 1 MLRA 36, Hasnah Mohammed Hashim FCJ in delivering the judgment of the court stated as follows:

F [41] The reason for the decision of the Court of Appeal is clearly inconsistent with legal principles applicable not only in actions involving trademark infringement and passing off but, also the *basic principle that parties are bound by their pleading.* The Court of Appeal departed from the well-trodden path of procedure. *Pleadings represents the cornerstone of any litigant's case. The court should confine its decision to the question raised in the pleadings. A court cannot make out a case not*
G *pleaded. Nor can it grant a relief which is not claimed.* The judicial commissioner had dealt with the issues before him extensively and applied the correct principles of trademark laws and passing off. (emphasis added)

H **[23]** Based on the above-established principles of the decided cases, it is crystal clear that the nature and scope of the plaintiffs' claim must be confined to what was expressly pleaded in the OS.

[24] The scope of the original pleading cannot be surreptitiously amended or enlarged by way of affidavit or submission. It is my view that the court's power to grant relief is not a *carte blanche* for parties to depart from their own
I pleaded case. The opposing party must be given fair notice of the case which they must meet.

[25] Therefore, applying the principles of law enunciated in the above case to our present case, I am of the view that the additional prayer raised by the plaintiffs at this stage ought not to be entertained by this court. The plaintiffs' claim must only be confined to what was expressly pleaded in the OS.

Plaintiffs' Omission To Pray For One Of The Reliefs In The Bahasa Melayu Version Compared To That In English

[26] It is to be noted that the plaintiffs have added relief in para. (d) in the English version of the OS when it was not provided for the same in the Bahasa Melayu version of the OS. The plaintiffs did not inform this court of their intention to amend the OS by inserting the relief claim nor were there any sufficient reasons given for the failure to state the relief sought in the Bahasa Melayu version when it was prayed for in the English version. For ease of reference, the relief would be reiterated below as follows:

> ...
>
> d) Kos; dan
>
> ...
>
> 13. The English translation of the plaintiffs' OS are as follows:
>
> d) Declarations, as appropriate, ensuing from the determinations and interpretation as aforesaid.

[27] Order 2 r. 1(1) of the Rules of Court 2012 provides that non-compliance with the requirement of these Rules shall be treated as an irregularity and shall not nullify the proceedings.

[28] For ease of reference, O. 2 r. 1(1) of the Rules of Court 2012 is held as follows:

> **Non-compliance with Rules (O. 2, r. 1)**
>
> 1. (1) Where, in beginning or purporting to begin any proceedings or at any stage in the course of or in connection with any proceedings, there has, by reason of anything done or left undone, been non-compliance with the requirement of these Rules, the non-compliance shall be treated as an irregularity and shall not nullify the proceedings, any step taken in the proceedings, or any document, judgment or order therein.

[29] However, in a recent Court of Appeal case of *Rekha Munisamy v. Ortus Expert White Sdn Bhd & Anor* [2021] 7 CLJ 353; [2021] 5 MLJ 836; [2021] 5 MLRA 189; Abu Bakar Jais (JCA) at paras. 44 to 50 of the judgment held as follows:

Whether the plaintiffs failed to translate the alleged defamatory statements into Bahasa Melayu

[44] There is no dispute the alleged defamatory statements by the defendant were in English. The defendant submitted these statements must be translated into Bahasa Melayu before the court. First, the defendant referred to O. 92 r. 1 of the ROC in support of this contention. It states as follows:

Language of documents (O. 92 r. 1)

(1) *Subject to para (2), any document required for use in pursuance of these rules shall be in the national language and may be accompanied by a translation thereof in the English language,* except that the translation for the purpose of O. 11 r. 6(4) and r. 7(1) shall be prepared in accordance with r. 6(5) of that order:

Provided that any document in the English language may be used as an exhibit, with or without a translation thereof in the national language.

(2) For Sabah and Sarawak, any document required for use in pursuance of these rules shall be in the English language and may be accompanied by a translation thereof in the national language except that the translation for the purpose of O. 11 r. 6(4) and r. 7(1) shall be prepared in accordance with r. 6(5) of that order.

[45] The defendant also referred to *s. 3 of the Interpretation Acts 1948 and 1967 (Consolidated and Revised 1989)* as to the meaning of 'national language'. This statutory provision states as follows:

'National Language' means the national language provided for by art. 152 of the Federal Constitution.

[46] In turn, *art. 152 of the Federal Constitution* states as follows:

(1) *The national language shall be the Malay language and shall be in such script as Parliament may by law provide …*

[47] The defendant also referred *to s. 8 of the National Language Act 1963/67 (Revised 1971)* in support of her contention on this point. The statutory provisions state as follows:

All proceedings (other than the giving of evidence by a witness) in the Federal Court, Court of Appeal, the High Court or any subordinate court shall be in the national language:

Provided that the court may either of its own motion or on the application of any party to any proceedings and after considering the interests of justice in those proceedings, order that the proceedings (other than the giving of evidence by a witness) shall be partly in the national language and partly in the English language.

[48] Referring also to the Court of Appeal case of *Dato' Seri Anwar bin Ibrahim v. Tun Dr Mahathir bin Mohamad* [2010] 2 MLJ 41, the defendant reiterated the importance of the translation and quoted Abdul Malik Ishak JCA (as he then was) in this case who said as follows:

[49] The importance of the Malay language as the national language cannot be taken lightly. Indeed Nik Hashim JC (later FCJ) in *Zainun bte Hj Dahan lwn. Rakyat Merchant Bankers Bhd & Satu Lagi* [1998] 1 MLJ 532 at pp. 535-536, emphasised the usage of the Malay language in our courts in these erudite terms:

Pemfailan 'notice of motion' ini dalam bahasa Inggeris bukan sahaja menyalahi A. 92 k. 1 KMT malah ia juga melanggar s. 8 Akta Bahasa Kebangsaan 1963/1967 ('Akta tersebut') yang memperuntukkan:

Segala prosiding (selain daripada pemberian keterangan oleh seseorang saksi) dalam Mahkamah Agung, Mahkamah Tinggi atau mana-mana mahkamah rendah hendaklah dalam bahasa kebangsaan:

Dengan syarat bahawa mahkamah boleh, sama ada atas kehendaknya sendiri atau atas permintaan mana-mana pihak dalam mana-mana prosiding dan selepas menimbangkan kepentingan keadilan dalam presiding itu, memerintahkan supaya presiding itu (selain daripada pemberian keterangan oleh seseorang saksi) dijalankan sebahagiannya dalam bahasa kebangsaan dan sebahagiannya dalam bahasa Inggeris.

Penggunaan Bahasa Melayu di mahkamah tidak boleh dipermudahkan dan diambil ringan. Perlembagaan Persekutuan menetapkan bahasa kebangsaan negara ialah Bahasa Melayu (perkara 152). Dengan peruntukan undang-undang di atas, maka keraguan atas penggunaan Bahasa Melayu dalam presiding mahkamah tidak boleh dipersoalkan lagi. Jadi, penggunaannya hendaklah dilaksanakan dengan ketatnya oleh semua pihak. Mahkamah hendaklah memainkan peranannya dengan melaksanakan kuasanya dengan sewajarnya. Kaedah-kaedah mahkamah termasuk A. 92 k. 1 adalah digubal bukan untuk hiasan tetapi untuk dipatuhi supaya presiding di mahkamah dapat berjalan dengan sempurna. Ketakpatuhan kepada peraturan atau kaedah-kaedah mahkamah akan membawa presiding di mahkamah menjadi kelam kabut (*Sykt Telekom Malaysia Bhd v. Business Chinese Directory Sdn Bhd* [1994] 2 MLJ 420; [1993] 3 CLJ 629).

Permohonan melalui notis usul bukan suatu perkara yang susah atau rumit untuk dibuat dalam Bahasa Melayu. Dalam kes ini, 'notice of motion' sengaja dibuat dan difailkan bersekali dengan afidavit serta pernyataan dalam bahasa Inggeris tanpa

memperdulikan peruntukan A. 92 k. 1 KMT, Akta tersebut dan Perlembagaan Persekutuan. Tidak ada sebab mengapa permohonan ini tidak boleh dibuat dalam Bahasa Melayu. Teks yang sahih ialah teks dalam Bahasa Melayu. Sekiranya mahkamah tidak berwaspada dan bertindak dari awal, sudah tentu lampiran 3 ini akan 'terlepas' dan pendengaran permohonan diteruskan tanpa mematuhi kaedah tersebut. Ketakpatuhan undang-undang tidak boleh dibiarkan. Permohonan di lampiran 3 adalah sungguh tidak teratur dan ia tidak boleh diterima dan dipertimbangkan oleh mahkamah sama sekali.

[50] We categorically say that the mandatory provisions of art. 152 of the Federal Constitution read together with s. 8 of the National Language Acts, 1963/1967 (Act 32) and s. 3 of the Interpretation Acts 1948 and 1967 (Act 388) must be adhered to. It requires the appellant to file the memorandum of appeal in the national language. No other language will be entertained. And the failure of the appellant to do so amounts to a blatant breach which would compel us to conclude that no memorandum of appeal has been filed at all. The purported memorandum of appeal in the English language must accordingly be rejected outright without further ado. What is mandatory, must be strictly adhered to. Otherwise dire consequences would follow.

[51] Indeed the salutary advice of Chang Min Tat J (as he then was) in *Yu Oi Yong & Anor v. Ho Toong Peng & Ors* [1977] 1 MLJ 120 at p. 121, must be heeded. There His Lordship said:

> There should, in my view, be some adherence to the rules of court, unless required by circumstances, if there is to be any meaning or purpose in such rules.
>
> It should I think, be realised by practitioners as well as by judges that while strict and slavish adherence to forms and rules can sometimes hinder the administration of justice, these forms and rules should not be disregarded for no reason whatsoever, since they embody the experience of the courts over the years in the cause ((*sic*) (course)) of speedy and efficient administration of justice.

[52] We observe that the word 'shall' appears in s. 8 of the National Language Acts 1963/1967 (Act 32). Likewise, the word 'shall' also appear in rr. 18(1) and 101 of the Rules of the Court of Appeal 1994. It is quite obvious that the use of the word 'shall' raises a presumption that the particular provision is imperative (*State of Uttar Pradesh v. Manbodhan Lai Srivastava* [1958] SCR 533 and *Manbodhan Lai Srivastava v. State of UP* [2021] 5 MLJ 836 at 855 AIR 1957 SC 912 at p 917; *State of Uttar Pradesh v. Babu Ram* AIR 1961 SC 751 at p. 765; *M/s Sainik Motors, Jodhpur & Ors v. State of Rajasthan* AIR 1961 SC 1480 at p. 1485; and *Govind Lai Chaggan Lai Patel v. The Agriculture Produce Market Committee & Ors*

AIR 1976 SC 263 at p. 267), and it is also ordinarily mandatory. It is also correct to say that when a statute uses the word 'shall', *prima facie* it is mandatory. And once it is held to be mandatory, the failure to comply with it will invalidate anything done under the statute.

[53] Thus, the failure on the part of the appellant to file a memorandum of appeal in Bahasa Malaysia renders the purported record of appeal filed by the appellant useless. It will not qualify as a record of appeal. It is our judgment that there is no proper or competent appeal before us.

[49] In the defamation case of *Lim Kit Siang v. Datuk Dr Ling Liong Sik & Ors* [1997] 5 MLJ 523, Zainun Ali JC later FCJ) held as follows:

> The authorities are manifest in their approach that it is fundamental that the exact words as uttered (by the first defendant in this case) *must be reproduced in the original language with a certified translation in the language of the court,* in the absence of which the claim will fail.

[50] The statutory provisions and case law authorities as narrated above, relied upon by the defendant on this point are quite clear in requiring such translation to be made by the plaintiffs. *These are cogent authorities supporting the defendant's contention that the alleged defamatory statements must be translated into Bahasa Melayu.* (emphasis added)

[30] Applying the abovementioned case to the present case, I view that the failure of the plaintiffs in praying for the reliefs in the national language, which is Bahasa Melayu meant that this court ought not to allow that said relief which was provided for the same in para. (d) of the English version. Even though the English version of the OS provides for such relief, this court is bound to give precedence to the Bahasa Melayu version.

[31] Besides, even though the abovementioned case was in respect of the failure to translate the court document from English to the national language, it is pertinent to note that O. 92 r. 1(1) of the Rules of Court 2012 had provided mandatory requirements for all court documents including the OS in this present case to be filed in Bahasa Melayu with translation to English allowed.

[32] It is pertinent to note that it is not uncommon for advocates and solicitors to prepare their pleadings or other court documents in English which would be subsequently translated into Bahasa Melayu and in the course of translating, such oversight would take place. As such, this court applies the words of Justice of the Court of Appeal, VC George at p. 490 in *Cheow Chew Khoon v. Abdul Johari Abdul Rahman* [1995] 4 CLJ 127; [1995] 1 MLJ 457; [1995] 1 MLRA 679; [1995] 1 AMR 759 that "this court will not, whenever feasible, allow a client to suffer for the negligence of his solicitor" would not dismiss such relief claimed in the English version despite failure to state the same in the Bahasa Melayu version.

[33] However, given that the requirement to file court documents in Bahasa Melayu being the national language is mandatory added with the fact that the plaintiffs have failed to provide reasonable justification or explanation for their failure to do the same as well as the non-application for the amendment of the Bahasa Melayu version of the OS would give this court the power not to allow the relief sought in para. (d) of the OS in the English version which was not in the Bahasa Melayu version. Allowing the said relief would lead to injustice to the defendants as parties would be able to claim for reliefs even though not claimed.

[34] In addition, in light of the recent Federal Court decision in *Munchy Food* (*supra*), I am of the view that this court could not grant the subsequent relief claimed by the plaintiffs when it was not claimed for the same in the Bahasa Melayu version. This court is also not bound to grant such declaratory relief under para. (e) of the Bahasa Melayu version for such further or other reliefs deemed fit by this court as allowing so might lead to this court going beyond the four corners of the parties' case.

Whether The OS Is An Attempt To Move The Civil Court To Pre-empt, Impede And/Or Interfere With The Ongoing Criminal Investigation Against The Second Plaintiff

[35] The defendants in the submission argued that the criminal justice system and the civil justice system are separate and the criminal issues are not to be tried and determined in a civil court by the civil process as doing so would amount to an invitation to the civil court to exercise criminal jurisdiction. To this, the defendants referred to the then Supreme Court case of *Government Of Malaysia v. Lim Kit Siang & Another Case* [1988] 1 CLJ 219; [1988] 1 CLJ (Rep) 63; [1988] 2 MLJ 12; [1988] 1 MLRA 178 and *Lai Soon Onn v. Chew Fei Meng & Other Appeals* [2018] 10 CLJ 48; [2018] 6 MLRA 633; [2019] 2 MLJ 96; [2018] 4 AMR 549.

[36] In the case of *Lim Kit Siang* (*supra*), Salleh Abas LP (as he then was) on pp. 76 to 77 (CLJ); pp. 26 to 27 (MLJ) held as follows:

> In this connection, we must remind ourselves of our true function in this appeal. We are not sitting as a criminal court holding a criminal trial nor are we hearing a criminal appeal. We are also not sitting as a commission of inquiry investigating into the wisdom, malpractices and misdeed of the government and its officials. We are only sitting as a ultimate civil court of appeal of the nation in which our duty is to deal only with such issues of law and facts as relate and are relevant to the case.
>
> As stated previously, the basis of the respondent's application for declaration is the allegation of corrupt practice by the Prime Minister and the two ministers. VC George J in the court below admirably dealt with the legal as well as factual aspects of the offence pertaining to the negotiation and formation of this contract and he finally came to the

conclusion that there were issues to be tried. But the question is: are these issues, which are in no uncertain term allegedly criminal, to be tried in a civil court by the civil process? Is the respondent's application not an invitation to the civil court to exercise criminal jurisdiction?

In *Gouriet*'s case, the House of Lords was confronted with a similar question. The House refused to allow the enforcement of criminal law by a civil court. Lord Diplock reminded the House of the importance of keeping a difference "between private law and public law" meaning, in the context of that case, civil law and criminal law. In the words of Lord Diplock, "it is the failure to recognize this distinction that has ... led to some confusion and an unaccustomed degree of rhetoric in this case". *I accept this approach in view of the separation of the system of criminal justice from that of the civil justice system. It is unacceptable that criminal law should be enforced by means of civil proceedings for a declaration when the court's power to grant that remedy is only at the discretion of the court. Jurisdiction of a criminal court is fixed and certain. The standard of proof in a criminal case is different from that required in a civil case and moreover the Attorney-General is the guardian of public interest and as the Public Prosecutor, he, not the court, is in control of all prosecutions.* How can a prosecution of this nature be done behind his back? *These are some of the most serious objections to the exercise by a civil court of its discretionary power relating to declaratory and injunctive remedies.* Our system requires the public to trust the impartiality and fair-mindedness of the Attorney-General. If he fails in his duty to exhibit this sense of fairness and to protect public interest which he is the guardian, the matter can be raised in Parliament or elsewhere. (emphasis added)

[37] In the case of *Lai Soon Onn* (*supra*), the Court of Appeal at paras. 39 to 41 held as follows:

[39] *By the very nature of the declaratory reliefs prayed for, essentially the plaintiff seeks a declaration that the defendants committed a criminal offence under the CMSA.* Before such a declaration can be made there must be a determination of a contravention. By filing his claim in the civil courts the plaintiff is seeking for such determination to be made by the civil court in a civil proceeding. Such cannot be the case. The burden of proof between the two is different. Essentially, it is not for the civil courts to intrude into the domain of the criminal court. That cannot be the intention of s. 357 of the CMSA.

[40] It is the attorney general who has the conduct of prosecutions and not the court. It is also the prerogative of the attorney general under art. 145(3) of the Federal Constitution to institute, conduct or discontinue any proceedings for an offence. By asking for the declaratory reliefs, the plaintiff is urging this court to usurp the powers of the public prosecutor, who has control of criminal prosecutions in the country. We agree with the submission of D3 that this is a collateral attempt to bypass the role of the attorney general, and if allowed will open floodgates to litigation of this nature.

A [41] *Criminal law cannot be enforced by civil proceedings to obtain a declaration that a criminal offence has been committed.* This principle is aptly ruled in *Government of Malaysia v. Lim Kit Siang* [1988] 2 MLJ 12, by Salleh Abas LP wherein he said that:

> *It is unacceptable that criminal law should be enforced by means of civil proceedings for a declaration when the court's powers to grant that remedy is only at the discretion of the court. Jurisdiction of a criminal court is fixed and certain.* The standard of proof in a criminal case is different from that required in a civil case and moreover the Attorney General is the guardian of public interest and as the public prosecutor, he, not the court, is in control of all prosecutions. (emphasis added)

[38] In the present case, it is evident that the plaintiffs are seeking the appropriate declaratory reliefs ensuing from the determinations as to whether the registered medical practitioner is entitled to and could dispense Ivermectin as an ingredient to his or her patient for purposes of the medical treatment of such patient only and in compliance under s. 19 of the Poisons Act 1952 read together with the Poison Regulations 1952.

[39] The plaintiffs in their submission in reply (encl. no. 25) submitted that the present OS was filed where there were facts concerning the second plaintiff were raised to show that the threat about the dispensing of Ivermectin is real and not illusory. To this, the plaintiffs referred to the case of *Datuk Syed Kechik Syed Mohamed v. Government Of Malaysia & Anor* [1978] 1 LNS 44; [1979] 2 MLJ 101; [1978] 1 MLRA 504, in arguing that there exists potential and a real threat posed to members of the medical profession.

[40] However, I am of the view that despite the plaintiffs' submission that this OS was initiated by MAAFIM which comprises a respectable body of qualified doctors and specialists, this present OS is without merit, frivolous and an abuse of the court process.

[41] In the case of *Protasco Bhd v. PT Anglo Slavic Utama & Ors* [2020] 1 LNS 997; [2020] 6 MLRH 491; [2020] MLJU 1413, Liza Chan Sow Keng JC referred to several cases on the definition of abuse of court process as follows:

> [88] As for the meaning of 'an abuse of the process of the court' reference is made to the case of *Gabriel Peter & Partners (suing as a firm) v. Wee Chang Jin* [1998] 1 SLR 374 at p. 384:
>
> The term 'abuse of the process of the Court', in Order 18 rule 19(1)(d), has been given a wide interpretation by the Courts. It includes considerations of public policy and the interests of justice. This term signifies that the process of the Court must be used *bona fide* and properly and must not be abused. The Court will prevent the improper use of its machinery. It will prevent the judicial process from being used as a means of vexation and oppression in the

process of litigation. The categories of conduct rendering a claim frivolous, vexatious or an abuse of process are not closed and will depend on all relevant circumstances of the case. A type of conduct which has been judicially acknowledged as an abuse of process is the bringing of an action for a collateral purpose ... if an action was not brought *bona fide* for the purpose of obtaining relief but for some other ulterior or collateral purpose, it might be struck out as an abuse of the process of the Court.

31. Gopal Sri Ram JCA (as he then was) in the case of *Malaysia Building Society Bhd v. Tan Sri General Ungku Nazaruddin Ungku Mohamed* [1998] 2 CLJ 340, at 352 said this in regard to the doctrine of abuse of process):

Every person who is aggrieved by some wrong he considers done him is at liberty to invoke the process of the court. Equally may a litigant invoke the process to enforce some claim which he perceives he has against another. *When however, the process of the court is invoked, not for the genuine purpose of obtaining the relief claimed, but for a collateral purpose, for example, to oppress the defendant, it becomes an abuse of process. Where the court's process is abused, the proceedings complained of may be stayed, or if it is too late to grant a stay, the party injured may bring an action based on the tort of collateral abuse of process.*

[89] The Supreme Court in *Raja Zainal Abidin bin Raja Haji Tachik & Ors v. British-American Life & General Insurance Bhd* [1993] 3 MLJ 16 pronounced that the court has an inherent jurisdiction to prevent an abuse of its process (SC). (emphasis added)

[42] Applying the case of *Protasco* (*supra*) to the present case, I am of the considered opinion that the filing of this present OS is an abuse of the court process where there exists a collateral purpose of interfering with the criminal investigation conducted against the second plaintiff. It is to be noted at this juncture that it is at the discretion of the Attorney General as to whether there exists a nexus to charge the second plaintiff for dispensing or selling the Ivermectin.

[43] It is pertinent to note that this falls within the jurisdiction of the criminal courts and not the civil courts. In interpreting the provisions under the Poisons Act 1952 read together with the Poison Regulations 1952 and making a subsequent declaration would amount to usurping the powers of the Attorney General in initiating or discontinuing the criminal case against the second plaintiff. This court ought to take note that there is currently an ongoing criminal investigation against the second plaintiff concerning the alleged commission of an offence for dispensing or sale of Ivermectin.

[44] Applying the abovementioned cases to this present case, I am of the considered opinion that determining the reliefs claimed by the plaintiffs would lead or potentially lead this court to pre-empt, impede and/or interfere with the ongoing criminal investigations against the second plaintiff. This is the same outcome even though no criminal charges have yet to be initiated against the second plaintiff. This would lead to the floodgate litigation where parties would attempt to bypass the criminal law and seek the determination of this court in the civil courts to interpret the criminal laws and procedures.

[45] The plaintiffs also submitted that even if the action of the second plaintiff is dismissed for the reason advanced by the defendants, the action by the first plaintiff remains intact. However, I am of a similar opinion as the action of the first plaintiff would fail because the present case would be within the jurisdiction of the criminal courts. In determining whether Ivermectin is legal and whether Ivermectin was dispensed by a registered medical practitioner in compliance with the Poisons Act 1952 read with the Poison Regulations 1952 and Control of Drugs and Cosmetics Regulations 1984, it will ultimately determine whether the first plaintiff comprising of medical professions and the second plaintiffs and more widely any medical profession could be charged under the Poisons Act 1952 read with the Poison Regulations 1952 and Control of Drugs and Cosmetics Regulations 1984 which are criminal offences.

[46] As such, I would agree with the submission of the defendants that the present OS ought to be dismissed because it is baseless and an abuse of the court process.

Whether The OS Is An Attempt To Move This Court To Make A New Public Health Policy To Permit The Use Of An Unregistered Poison For The Treatment Of COVID-19, Contrary To The Regulatory Regime And The Policy Of The Second Defendant

[47] At the outset, I would refer to the circular dated 4 August 2021 issued by the second defendant. The circular states as follows:

A

B

PEJABAT PENGARAH KANAN PERKHIDMATAN FARMASI
OFFICE OF THE SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Lot 36, Jalan Universiti, Petaling Jaya
46200 SELANGOR
MALAYSIA

Tel : 03-7841 3901
Faks : 03-7968 2048
Portal Rasmi : www.pharmacy.gov.m
E-mel : pejabatkpf@moh.gov.my

Ruj Tuan :
Ruj Kami : KKM 600-18/2/80 (4) Jld 5
Tarikh : 4 Ogos 2021

C

SEPERTI SENARAI EDARAN

Tuan/ Puan,

PEMAKLUMAN AKTIVITI PENGIMPORTAN, PENGIKLANAN, PENJUALAN DAN PENGILANGAN TERMASUK *COMPOUNDING* IVERMECTIN SEBAGAI PRODUK UNTUK RAWATAN JANGKITAN COVID-19 HANYA UNTUK PERCUBAAN KLINIKAL

D

Saya dengan hormatnya merujuk perkara di atas.

2. Ketua Pengarah Kesihatan Malaysia telah mengeluarkan kenyataan akhbar pada 18 Mei 2021 berkaitan "Salah Faham Mengenai Penggunaan Produk Ivermectin Sebagai Rawatan dan Pencegahan COVID-19 di Malaysia". Kementerian Kesihatan Malaysia (KKM) dalam kenyataan akhbar tersebut :

E

i) Menasihatkan orang ramai supaya **tidak mengambil** Ivermectin untuk tujuan rawatan dan pencegahan COVID-19 berikutan **tiada data klinikal bagi membuktikan keberkesanan penggunaannya** dalam rawatan dan pencegahan COVID-19.

ii) Bahagian Regulatori Farmasi Negara (NPRA) memaklumkan bahawa setakat ini tiada produk dengan bahan aktif Ivermectin berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD) untuk kegunaan manusia.

iii) Setakat ini, *World Health Organization* (WHO) hanya membenarkan Ivermectin sebagai rawatan COVID-19 dalam **kajian/ percubaan klinikal sahaja**.

F

iv) Memandangkan penularan wabak COVID-19 semakin meningkat di Malaysia, KKM tiada halangan untuk penggunaan **produk tidak berdaftar Ivermectin bagi tujuan percubaan klinikal sahaja** di Malaysia.

3. Sehubungan dengan itu, dengan merujuk kepada polisi KKM melalui kenyataan akhbar tersebut yang menyatakan KKM tiada halangan untuk penggunaan **produk tidak berdaftar Ivermectin hanya bagi tujuan percubaan klinikal sahaja** di Malaysia, adalah menjadi tanggungjawab semua ahli farmasi berlesen untuk memastikan semua aktiviti **pengimportan atau penjualan bahan mentah Ivermectin bagi tujuan pengilangan atau *compounding* produk bagi merawat jangkitan COVID-19 dan pengimportan atau penjualan produk yang mengandungi Ivermectin bagi merawat jangkitan COVID -19 adalah terhad bagi tujuan percubaan klinikal sahaja**

G

H

I

A

dengan mematuhi semua keperluan perundangan dan regulatori yang ditetapkan bagi tujuan tersebut. Sebarang bentuk pengiklanan produk racun termasuk ivermectin adalah tidak dibenarkan sama sekali kerana bertentangan dengan dasar dan polisi Lembaga Iklan Ubat (LIU).

B

4. Oleh yang demikian pihak tuan/puan perlu memastikan aktiviti pengimportan, pengilangan termasuk *compounding* dan penjualan bahan mentah Ivermectin atau produk yang mengandungi ivermectin bagi tujuan rawatan jangkitan COVID-19 selain di bawah percubaan klinikal yang dibenarkan perlu dihentikan dengan serta – merta. Manakala pengiklanan berkaitan bahan atau produk ini juga perlu dihentikan segera dan tidak diulang siar dalam mana-mana media.

C

5. Pihak kami berharap pemakluman ini dapat disampaikan kepada semua ahli farmasi berdaftar di seluruh negara bagi memastikan pengimportan, pengiklanan dan penjualan bahan mentah atau produk Ivermectin oleh ahli farmasi berlesen adalah mematuhi undang – undang yang dikuatkuasakan serta polisi yang ditetapkan oleh KKM seterusnya dapat bersama – sama mencegah penggunaan yang tidak sah produk Ivermectin dalam memastikan rakyat mendapat hanya produk yang berkualiti, selamat dan berkesan.

D

6. Pihak kami sentiasa menjalankan pemantauan berkaitan perkara ini dan tindakan penguatkuasaan akan diambil sekiranya didapati penjualan atau pembekalan serta pengiklanan ubat yang tertakluk kepada kawalan di bawah Akta Racun 1952, Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 dan Akta Ubat (iklan dan Penjualan) 1956, tidak mematuhi perundukan undang – undang yang dikuatkuasakan.

7. Kerjasama pihak tuan/ puan berkaitan perkara ini amatlah dihargai.

Sekian, terima kasih.

E

"PRIHATIN RAKYAT: DARURAT MEMERANGI COVID-19"

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

F

(DR. ROSHAYATI BINTI MOHAMAD SANI) RPh. 1449
Pengarah Bahagian Regulatori Farmasi Negara
b.p Pengarah Kanan Perkhidmatan Farmasi

G

[48] The defendants submitted that the regulatory regime for the sale and use of drugs and poisons is found in the Poisons Act 1952, Sale of Drugs Act 1952 and their respective regulations.

H

[49] The defendants also submitted that these statutory instruments comprise the regulatory framework. The sale and supply of drugs and poisons are subject to all the requirements found within the entirety of this framework.

I

[50] It is to be noted that the plaintiffs did not challenge the validity of any provision within the regulatory framework. The plaintiffs in their submission stated that "The real poser raised by this case is: whether the relevant Act(s)

gives doctors a vested right and autonomy to treat their patients through the administration of permissible drugs on a case-by-case basis. This involves an interpretation of the existing laws and regulations".

[51] I am of the view that it is a matter of interpretation of the relevant and governing statutory instruments pertaining to the investigation of the alleged offence committed in this instant case which involves the Poisons Act 1952 and Sale of Drugs Act 1952 and the regulations contained therein. Bearing in mind that in Malaysia, a registered practitioner is allowed to prescribe as well as dispense and/or sell medicine as happened in the instant case. Therefore, I view that both the Poisons Act 1952 and the Sale of Drugs Act 1952 and their regulations must be read conjunctively. The plaintiffs cannot selectively invite the court to interpret selected provisions of the Acts of their regulations as this does not conform to the established principle of judicial interpretation.

[52] I shall now look at reg. 7(1) of the Control of Drugs and Cosmetics Regulations 1984 (1984 Regulations) which was made under the Sale of Drugs Act 1952. It reads:

> **Prohibition against manufacture, sale, supply, importation, possession and administration**
>
> 7(1) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administrator any product unless:
>
> (a) the product is a registered product; and
>
> (b) the person holds the appropriate licence required and issued under these Regulations.

[53] Regulation 7(1) of the 1984 Regulations expressly prohibits the sale and supply of any product, subject to two requirements that the product must be a registered product and the person must have a licence.

[54] The second requirement is subject to certain exemptions in reg. 15(2) of the 1984 Regulations. Specifically, "as regard a licence to supply and manufacture," the second requirement in reg. 7(1) of the 1984 Regulations does not apply to the dispensation of a drug by a medical practitioner for the purposes of it being used for the medical treatment of their patients. However, there is no exemption for the first requirement under reg. 15(2) of the 1984 Regulations.

[55] The defendants stated that at present, no product with Ivermectin as an active ingredient has been registered with the Drug Control Authority for human use. The present regulatory requirements are clear since Ivermectin products are not registered in the first place, there is no question of them being supplied for human use, whether by a medical practitioner for the treatment of his patients or otherwise.

[56] To date, the use of Ivermectin for the treatment of COVID-19 is only permitted for clinical trials subject to the approval of the Ministry of Health. This is in line with the guidance of the World Health Organisation (WHO). Clinical trials to establish the efficacy and the effectiveness of Ivermectin in this regard have yet to be concluded. This is also supported by the circular dated 4 August 2021 (*supra*) from the second defendant which clearly states that:

> (i) Menasihatkan orang ramai supaya tidak mengambil Ivermectin untuk tujuan rawatan dan pencegahan COVID-19 berikutan tiada data klinikal bagi membuktikan keberkesanan penggunaannya dalam rawatan dan pencegahan COVID-19.
>
> (ii) Bahagian Regulatori Farmasi Negara (NPRA) memaklumkan bahawa setakat ini tiada produk dengan aktif Ivermectin berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD) untuk kegunaan manusia.
>
> (iii) Setakat ini, World Health Organisation (WHO) hanya membenarkan Ivermectin sebagai rawatan COVID-19 dalam kajian/ percubaan klinikal sahaja.
>
> (iv) Memandangkan penularan wabak COVID-19 semakin meningkat di Malaysia, KKM tiada halangan untuk penggunaan produk tidak berdaftar Ivermectin bagi tujuan percubaan klinikal sahaja di Malaysia.

[57] With the issuance of the circular, the defendants as the authority are making a specific policy on the use of Ivermectin for public health and safety concerns during the unprecedented pandemic. Undisputedly, the formulation of policy in the public interest is the business of the elected branches.

[58] The decisions of Government call for wider considerations, taking into account the conflicting interests and the needs of the community as a whole. The policy-making process is necessarily future-oriented, flexible, and can be swiftly changed to adapt to changing circumstances. These characteristics render the Government best placed to make policy decisions.

[59] On the contrary, the administration of justice is the business of the court. The determination by the court is focused on the rights and duties of the parties before it, considering the circumstances and evidence of the case.

[60] The importance of recognising the respective institutional competence of the court and the Government was stressed by the Federal Court in *Dr Michael Jeyakumar Devaraj v. Peguam Negara Malaysia* [2013] 2 CLJ 1009; [2013] 2 MLJ 321; [2013] 2 MLRA 179; [2013] 3 AMR 315; where Raus Sharif PCA (later CJ) held:

> … It is our view that the courts is in no position to evaluate the qualifications in the application for the Special Constituency Allocation and to determine or decide on the policy made by the executive. *We have to take cognisance of the fact that government policies emanate after consideration of a number of technical factors which are often non legal; and judges do not possess the necessary information and expertise to evaluate these non-legal factors and to pass judgment on the appropriateness or adequacy of a particular policy.*
>
> > *… On matters affecting policy and requiring technical expertise, the court would leave the matter for decision of those who are qualified to address this issue.* Unless the policy or action is inconsistent with the constitution and the laws or arbitrary or irrational or abuse of power, the court will not interfere with such matters
>
> *… Clearly, what was decided by the second respondent hinged on matters relating to policy and thus we would dissuade ourselves from entering into the realm which belongs to the executive. Courts must be wary of unduly extending its judicial arms to policy matters which are exclusively within the domain of the executive.* Unwarranted usurpation and transgression by the judiciary into the realm of the executive and *vice versa* will bring about disrepute to our system of government which upholds the separation of powers between the three main components *vis a vis* the executive, the legislature and the judiciary. (emphasis added)

Recent Decisions Involving Arguments On Ivermectin

[61] The limits of the court's role and institutional competence are apparent in the context of measures to deal with the COVID-19 pandemic. The pandemic gave rise to public health emergencies at a national and global level. Policy measures in respect of COVID-19 must necessarily be highly flexible, adapted based on every new development in scientific and medical knowledge, based on the collective experience of the world in dealing with a novel and deadly virus. The nature of the judicial process of past-oriented, relatively unchanging, and focused on legal rights and liabilities in a particular dispute is inherently unsuited for this exercise.

[62] Similar arguments on Ivermectin have been rejected in several recent cases on COVID-19 policy measures.

[63] In *SD v. Royal Borough Of Kensington And Chelsea* [2021] EWCOP 14, the England and Wales Court of Protection heard an application concerning the welfare of V, an elderly lady living in a care home. The applicant, V's daughter, sought a declaration that it would be unlawful to administer V with a vaccine against COVID-19. In support thereof, the applicant relied on the viability and potential of Ivermectin as a solution against COVID-19. The court rejected the argument and held that it was in V's best interest to receive a COVID-19 vaccine. Hayden J stated:

A *... Ivermectin has not, at least as yet, achieved credibility with any public health authority, as a treatment for Covid-19; oral ivermectin appears to be an unlicensed treatment for some forms of scabies and other parasites. I found it striking that SD rejected the overwhelming view of the public health authorities in relation to the certified vaccines, speculating about the risks of unforeseen side effects or adverse reactions, yet wholeheartedly embraced the unquantifiable risks of an unlicensed and*
B *unendorsed drug.*

31. I explained to SD that *it is not the function of the Court of Protection to arbitrate medical controversy or to provide a forum for ventilating speculative theories.* My task is to evaluate V's situation in light of the authorised, peer-reviewed research and public health guidelines, and
C to set those in the context of the wider picture of V's best interests. (emphasis added)

[64] In *Athvale v. New South Wales* [2021] FAC 1075, the Federal Court of Australia heard an application for injunctive relief against the State's policy on social distancing and gatherings, which restricted the applicants from
D celebrating certain religious events. In support thereof, the applicants relied on expert evidence by Professor Borody that Ivermectin was a cheap and effective COVID-19 treatment. The court rejected the argument and dismissed the application. It was noted that Ivermectin is not an approved medication for the treatment of COVID-19, having not been through the
E approval process of the Therapeutic Good Administration. Griffiths J held:

The terms of the State instruments represent the weighing or balancing of competing interests by the maker of the instrument, whose objective is to protect the public and its institutions from deleterious effects of the COVID-19 pandemic, while also recognising the justification for some limited exceptions to that protection. Plainly this involves an evaluative
F judgment with a heavy political and policy content. ... *Their challenge impermissibly invites the Court to determine on the merits complex policy choices. ... As I have repeatedly emphasised, it is not the Court's task to engage in a merits review of those policy choices. Those choices require a balance between competing interests. A primary interest will be public health and public protection but other*
G *interests need to be balanced. It is a matter for the executive and not the Court to strike that balance.* (emphasis added)

[65] Similarly in *Kassam and others v. Hazzard and others* [2021] 393 ALR 664, the court noted that the Therapeutic Goods Administration had expressly stated that "there was insufficient evidence to support the safe and
H effective use of Ivermectin", and that the policy of the Minister was "Ivermectin cannot be used in humans for COVID-19 until further testing and clinical trials have been completed to show that it is safe and effective in human". Beech-Jones CJ emphasised that:

It is important to note that it is not the Court's function to determine the
I merits of the exercise of the power by the Minister to make the impugned orders, much less for the Court to choose between plausible responses to the risks to the public health posed by the Delta variant. It is also not the

Court's function to conclusively determine the effectiveness of some of the alleged treatments for those infected or the effectiveness of COVID-19 vaccines especially their capacity to inhibit the spread of the disease. These are all matters of merits, policy and fact for the decision maker and not the Court.

[66] Considering that the investigation of this instant case is ongoing and it is an undisputed fact that Ivermectin is not a registered product. I am of the view that this OS would be tantamount to moving the court to make a new public health policy to permit the use of an unregistered poison including and not restricted to the treatment of COVID-19 which is contrary to the regulatory regime and the policy of the second defendant.

Conclusion

[67] As such, with the use and effect of the Ivermectin drugs still pending further clinical research at the World Health Organisation (WHO) with no assurance that Ivermectin could be used to cure COVID-19, it is defying the interest of justice to legitimise the use and dispensation of Ivermectin by registered medical profession under the Poisons Act 1952 and the Poison Regulations 1952. I am of the considered opinion that it is within the jurisdiction of the Legislature and the Executive to make such a declaration of the legitimacy of the use of Ivermectin on humans and it is not within the powers of this court to do so.

[68] I am of the considered view that the effect of the plaintiffs' claim is to pre-empt and interfere with the ongoing criminal investigation against the second plaintiff by determining the question of criminality. It is not the role of the civil court to usurp the jurisdiction of the criminal courts and the prosecutorial discretion of the Public Prosecutor and the essence of the plaintiffs' claim is for this court to make a new public health policy in respect of Ivermectin, contrary to the regulatory framework and Government policy and without expert scientific evidence.

[69] It is not the role of the court to determine policy issues in the field of scientific and technical expertise, especially in the rapidly evolving circumstances of the COVID-19 pandemic.

[70] Accordingly, based on the aforesaid reasons, I dismissed the plaintiffs' OS (encl. 1) with costs of RM5,000.